



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:

Anurag RATHORE et al.

Atty. Docket No.: 161765.00520  
(01113/US)

Serial No.: 10/646,798

Group Art Unit: 1626

Filed: August 25, 2003

Examiner: TBA

For: Method for the Preparation of Growth Hormone and Antagonist Thereof  
Having Lower Levels of Isoform Impurities Thereof

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. §§ 1.56(a), 1.97 and 1.98 *et seq.*, Applicants submit herewith the attached Form PTO/SB/08A. The listed documents were cited in the specification of the application. Applicants have submitted herewith a copy each of the references cited on the attached Form PTO/SB/08A except for the U.S. patents. Applicants respectfully request that the Examiner consider and enter all the documents cited on the enclosed Form PTO/SB/08A into the file of the above-identified application. Applicants also request an indication of the same by return of the Form PTO/SB/08A being initialed and dated by the Examiner.

No fees are believed due to ensure consideration of the attached documents by the Examiner. However, if any fees are required or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 19-0733, as necessary.

Respectfully submitted,

Date: April 21, 2004

By:

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Attachments:

Form PTO/SB/08A  
References Cited on Form PTO/SB/08A

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PATENT & TRADEMARK OFFICE

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031  
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

|       |   |    |   |                        |                         |
|-------|---|----|---|------------------------|-------------------------|
| Sheet | 1 | of | 1 | Attorney Docket Number | 161765.00520 (01113/US) |
|-------|---|----|---|------------------------|-------------------------|

### Complete if Known

|                      |                       |
|----------------------|-----------------------|
| Application Number   | 10/646,798            |
| Filing Date          | August 25, 2003       |
| First Named Inventor | Anurag RATHORE et al. |
| Group Art Unit       | 1626                  |
| Examiner Name        | TBA                   |

| U.S. PATENT DOCUMENTS |                       |   |                                |   |   |
|-----------------------|-----------------------|---|--------------------------------|---|---|
| Examiner Initials *   | Cite No. <sup>1</sup> | Document Number<br>Number - Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|                       |                       | US-5,849,535  | 12/15/1998                     | Cunningham et al.                               |   |
|                       |                       | US- 6,057,292   | 05/02/2000                     | Cunningham et al.                               |   |
|                       |                       | US-   |                                |   |   |
|                       |                       | US-   |                                |   |   |

| FOREIGN PATENT DOCUMENTS |                       |  |                                |   |   |                |
|--------------------------|-----------------------|--|--------------------------------|---|---|----------------|
| Examiner Initials *      | Cite No. <sup>1</sup> | Foreign Patent Document<br>Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T <sup>6</sup> |
|                          |                       | WO 96/02570  | 02/01/96                       |   |   |                |
|                          |                       | WO 02/27478  | 07/25/02                       |   |   |                |
|                          |                       |  |                                |   |   |                |
|                          |                       |  |                                |   |   |                |
|                          |                       |  |                                |   |   |                |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS |                       |   |  |  |  |                |
|--|-----------------------|---|--|--|--|----------------|
| Examiner Initials *                                | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  |  |  | T <sup>2</sup> |
|  |                       | Andersson et al., "Isolation and characterization of a trisulfide variant of recombinant human growth hormone formed during expression in <i>Escherichia coli</i> ," Int. J. Peptide Protein Res. 47:311-321 (1996).  |  |  |  |                |
|  |                       | J. Houk and G.M. Whitesides, "Structure-Reactivity Relations for Thiol-Disulfide Interchange," J. M. Chem. Soc., 109:6825-6836 (1987).  |  |  |  |                |
|  |                       | A. Jesperson et al., "Characterisation of a trisulphide derivative of biosynthetic human growth hormone produced in <i>Escherichia coli</i> ," Eur. J. Biochem. 219:365-373 (1994).   |  |  |  |                |
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|  |                       | The Merck Index, 12 <sup>th</sup> Edition, S. Budavari (Editor), Merck & Co., Inc., Therapeutic Category and Biological Activity Index, p. THER-19 (under "CHELATING AGENT"), Whitehouse Station, NJ (1996).  |  |  |  |                |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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